WEST VIRGINIA CODE CHAPTER 16b ARTICLE 7

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§16B-7-1. Purpose and short title.

This article shall be known as the Chronic Pain Clinic Licensing Act. The purpose of this act is to establish licensing requirements for facilities that treat patients for chronic pain management in order to ensure that patients may be lawfully treated for chronic pain by physicians in facilities that comply with oversight requirements developed by the Office of the Inspector General.

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§16B-7-2. Definitions.

(a) As used in this article, unless a different meaning appears from the context:

(1) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. For purposes of this article, "chronic pain" does not include pain directly associated with a terminal condition.

(2) "Director" means the Director of the Office of Health Facility Licensure and Certification, or his or her designee.

(3) "Inspector General" means the Inspector General of the Office of the Inspector General as described in §16B-2-1 of this code, or his or her designee.

(4) "Office of Health Facility Licensure and Certification" means the West Virginia Office of Health Facility Licensure and Certification within the Office of the Inspector General.

(5) "Owner" means any person, partnership, association, or corporation listed as the owner of a pain management clinic on the licensing forms required by this article.

(6) "Pain management clinic" means all privately-owned pain management clinics, facilities, or offices not otherwise exempted from this article and which meet both of the following criteria:

(A) Where in any month more than 50 percent of patients of the clinic are prescribed or dispensed Schedule II opioids or other Schedule II controlled substances specified in rules promulgated pursuant to this article for chronic pain resulting from conditions that are not terminal; and

(B) The facility meets any other identifying criteria established by the Inspector General by rule.

(7) "Physician" means an individual authorized to practice medicine or surgery or osteopathic medicine or surgery in this state.

(8) "Prescriber" means an individual who is authorized by law to prescribe drugs or drug therapy related devices in the course of the individual’s professional practice, including only a medical or osteopathic physician authorized to practice medicine or surgery; a physician assistant, or osteopathic physician assistant who holds a certificate to prescribe drugs; or an advanced nurse practitioner who holds a certificate to prescribe.

(b) The Inspector General may define in rules any term or phrase used in this article which is not expressly defined.

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§16B-7-3. Pain management clinics to obtain license; application; fees and inspections.

(a) The Inspector General designates the Director of the Office of Health Facility Licensure and Certification to enforce the provisions of this article, except where otherwise stated.

(b) No person, partnership, association, or corporation may operate a pain management clinic without first obtaining a license from the director in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.

(c) Any person, partnership, association, or corporation desiring a license to operate a pain management clinic in this state shall file with the Office of Health Facility Licensure and Certification an application in such form as the director shall prescribe and furnish accompanied by a fee to be determined by the director.

(d) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect each facility prior to issuing a license and review all documentation submitted with the application. The director shall issue a license if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated pursuant to this article.

(e) A license shall expire one year from the date of issuance. Sixty days prior to the expiration date, an application for renewal shall be submitted on forms furnished by the director. A license shall be renewed if the director determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A license issued to one facility pursuant to this article is not transferable or assignable. A change of ownership of a licensed pain management clinic requires submission of a new application.

(f) The director or his or her designee shall inspect on a periodic basis all pain management clinics that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.

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§16B-7-4. Operational requirements.

(a) Any person, partnership, association, or corporation that desires to operate a pain management clinic in this state must submit to the director documentation that the facility meets all of the following requirements:

(1) The clinic shall be licensed in this state with the director, the Secretary of State, the State Tax Department, and all other applicable business or license entities.

(2) The application shall list all owners of the clinic. At least one owner shall be a physician actively licensed to practice medicine, surgery, or osteopathic medicine or surgery in this state. The clinic shall notify the director of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(3) Each pain management clinic shall designate a physician owner who shall practice at the clinic and who will be responsible for the operation of the clinic. Within 10 days after termination of a designated physician, the clinic shall notify the director of the identity of another designated physician for that clinic. Failing to have a licensed designated physician practicing at the location of the clinic may be the basis for a suspension or revocation of the clinic license. The designated physician shall:

(A) Have a full, active, and unencumbered license to practice medicine, surgery, or osteopathic medicine or surgery in this state:

(B) Meet one of the following training requirements:

(i) Complete a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or such other similar program as may be approved by the director; or

(ii) Hold current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology or such other board certification as may be approved by the director.

(C) Practice at the licensed clinic location for which the physician has assumed responsibility;

(D) Be responsible for complying with all requirements related to the licensing and operation of the clinic;

(E) Supervise, control, and direct the activities of each individual working or operating at the facility, including any employee, volunteer, or individual under contract, who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment. The supervision, control, and direction shall be provided in accordance with rules promulgated by the Inspector General.

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(4) All persons employed by the facility shall comply with the requirements for the operation of a pain management clinic established by this article or by any rule adopted pursuant to this article.

(5) No person may own or be employed by or associated with a pain management clinic who has previously been convicted of, or pleaded guilty to, any felony in this state or another state or territory of the United States. All owners, employees, volunteers, or associates of the clinic shall undergo a criminal records check prior to operation of the clinic or engaging in any work, paid or otherwise, pursuant to §16B-15-1 *et seq*. of this code.

(6) The clinic may not be owned by, nor may it employ or associate with, any physician or prescriber:

(A) Whose Drug Enforcement Administration number has ever been revoked;

(B) Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or

(C) Who, in any jurisdiction of this state or any other state or territory of the United States, has been convicted of or plead guilty or nolo contendere to an offense that constitutes a felony for receipt of illicit and diverted drugs, including controlled substances, as defined by §60A-1-101 of this code.

(7) A person may not dispense any medication, including a controlled substance, as defined by section §60A-1-101 of this code, on the premises of a licensed pain management clinic unless he or she is a physician or pharmacist licensed in this state. Prior to dispensing or prescribing controlled substances, as defined by §60A-1-101 of this code, at a pain management clinic, the treating physician must access the Controlled Substances Monitoring Program database maintained by the Board of Pharmacy to ensure the patient is not seeking controlled substances from multiple sources. If the patient receives ongoing treatment, the physician shall also review the Controlled Substances Monitoring Program database at each patient examination or at least every 90 days. The results obtained from the Controlled Substances Monitoring Program database shall be maintained with the patient's medical records.

(8) Each clinic location shall be licensed separately, regardless of whether the clinic is operated under the same business name or management as another clinic.

(9) A pain management clinic shall not dispense to any patient more than a 72-hour supply of a controlled substance, as defined by §60A-1-101 of this code.

(10) The pain management clinic shall develop patient protocols, treatment plans, and profiles, as prescribed by the Inspector General by rule, and which shall include, but not be limited by, the following guidelines:

(A) When a physician diagnoses an individual as having chronic pain, the physician may treat

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the pain by managing it with medications in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain unless the individual has been previously diagnosed as suffering from chronic pain and is referred to the pain management clinic by such diagnosing physician. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care.

(B) The physician shall maintain a record of all of the following:

(i) Medical history and physical examination of the individual;

(ii) The diagnosis of chronic pain, including signs, symptoms, and causes;

(iii) The plan of treatment proposed, the patient's response to the treatment, and any modification to the plan of treatment;

(iv) The dates on which any medications were prescribed, dispensed, or administered, the name and address of the individual to or for whom the medications were prescribed, dispensed, or administered and the amounts and dosage forms for the drugs prescribed, dispensed, or administered; and

(v) A copy of the report made by the physician to whom referral for evaluation was made.

(C) A physician, physician assistant, certified registered nurse anesthetist, or advanced nurse practitioner shall perform a physical examination of a patient on the same day that the physician initially prescribes, dispenses or administers a controlled substance to a patient, and at least four times a year thereafter at a pain management clinic according to accepted and prevailing standards for medical care.

(D) A physician authorized to prescribe controlled substances who practices at a pain management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The physician shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by statute or rule, the physician shall notify the director in writing within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(c) Upon satisfaction that an applicant has met all of the requirements of this article, the director may issue a license to operate a pain management clinic. An entity that obtains this license may possess, have custody or control of, and dispense drugs designated as Schedule II or Schedule III in §60A-2-206 or §60A-2-208 of this code.

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§16B-7-5. Exemptions.

(a) The following facilities are not pain management clinics subject to the requirements of this article:

(1) A facility that does not prescribe or dispense controlled substances for the treatment of chronic pain;

(2) A hospital licensed in this state, a facility located on the campus of a licensed hospital that is owned, operated, or controlled by that licensed hospital, and an ambulatory health care facility as defined by §16-2D-2 of this code that is owned, operated, or controlled by a licensed hospital;

(3) A physician practice owned or controlled, in whole or in part, by a licensed hospital or by an entity that owns or controls, in whole or in part, one or more licensed hospitals;

(4) A hospice program licensed in this state;

(5) A nursing home licensed in this state;

(6) An ambulatory surgical facility as defined by §16-2D-2 of this code; and

(7) A facility conducting clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(b) Any facility that is not included in this section may petition to the director for an exemption from the requirements of this article. All such petitions are subject to the administrative procedures requirements of §29A-1-1 *et seq*. of this code.

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§16B-7-6. Inspection.

(a) The Office of Health Facility Licensure and Certification shall inspect each pain management clinic annually, including a review of the patient records, to ensure that it complies with this article and the applicable rules.

(b) During an onsite inspection, the inspector shall make a reasonable attempt to discuss each violation with the designated physician or other owners of the pain management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the designated physician or other owners of the pain management clinic and verified by follow-up visits by the Office of Health Facility Licensure and Certification.

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§16B-7-7. Suspension; revocation.

(a) The director, in consultation with the Inspector General, may suspend or revoke a license issued pursuant to this article if the provisions of this article or of the rules promulgated pursuant to this article are violated. The director, in consultation with the Inspector General, may revoke a clinic's license and prohibit all physicians associated with that pain management clinic from practicing at the clinic location based upon an annual or periodic inspection and evaluation.

(b) Before any such license is suspended or revoked, however, written notice shall be given to the licensee, stating the grounds of the complaint and shall provide notice of the right to request a hearing. The notice shall be sent by certified mail to the licensee at the address where the pain management clinic concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.

(c) If a license is revoked pursuant to this article, a new application for a license may be considered by the director if, when, and after the conditions upon which revocation was based have been corrected, and evidence of this fact has been furnished to the director. A new license may then be granted after proper inspection has been made and all provisions of this article and rules promulgated pursuant to this article have been satisfied.

(d) All of the pertinent provisions of §29A-5-1 *et seq*. of this code shall apply and govern any hearing authorized and required by the provisions of this article and the administrative procedure in connection therewith.

(e) Any applicant or licensee who is dissatisfied with the decision of the Board of Review as a result of the hearing provided in this section may, within 30 days after receiving notice of the decision, appeal the decision to West Virginia Intermediate Court of Appeals for judicial review of the decision.

(f) The court may affirm, modify, or reverse the decision of the Board of Review and either the applicant or licensee or the Inspector General may appeal from the court's decision to the Supreme Court of Appeals.

(g) If the license of a pain management clinic is revoked or suspended, the designated physician of the clinic, any other owner of the clinic or the owner or lessor of the clinic property shall cease to operate the facility as a pain management clinic as of the effective date of the suspension or revocation. The owner or lessor of the clinic property is responsible for removing all signs and symbols identifying the premises as a pain management clinic within 30 days.

(h) Upon the effective date of the suspension or revocation, the designated physician of the pain management clinic shall advise the director and the Board of Pharmacy of the disposition of all drugs located on the premises. The disposition is subject to the supervision and approval of the director. Drugs that are purchased or held by a pain management clinic

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that is not licensed may be deemed adulterated.

(i) If the license of a pain management clinic is suspended or revoked, any person named in the licensing documents of the clinic, including persons owning or operating the pain management clinic, may not, as an individual or as part of a group, apply to operate another pain management clinic for five years after the date of suspension or revocation.

(j) The period of suspension for the license of a pain management clinic shall be prescribed by the director, in consultation with the Inspector General, but may not exceed one year.

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§16B-7-8. Violations; penalties; injunction.

(a) Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a pain management clinic without first obtaining a license therefor as herein provided, or which violates any provisions of this article or any rule lawfully promulgated pursuant to this article, shall be assessed a civil penalty by the director, in consultation with the Inspector General, in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(1) If a pain management clinic or any owner or designated physician is found to be in violation of any provision of this article, unless otherwise noted herein, the director, in consultation with the Inspector General, may suspend or revoke the clinic's license.

(2) If the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation, the director, in consultation with the Inspector General, may impose a civil penalty not to exceed $10,000, and, in the case of an owner-operated pain management clinic, revoke or deny a pain management clinic's license.

(3) If an owner or designated physician of a pain management clinic concurrently operates an unlicensed pain management clinic, the director, in consultation with the Inspector General, may impose a civil penalty upon the owner or physician, or both, not to exceed $5,000 per day.

(4) If the owner of a pain management clinic that requires a license under this article fails to apply for a new license for the clinic upon a change-of-ownership and operates the clinic under the new ownership, the director, in consultation with the Inspector General, may impose a civil penalty not to exceed $5,000.

(5) If a physician knowingly operates, owns, or manages an unlicensed pain management clinic that is required to be licensed pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or dispensed, controlled substances in an unlicensed pain management clinic that is required to be licensed; or licenses a pain management clinic through misrepresentation or fraud; procures or attempts to procure a license for a pain management clinic for any other person by making or causing to be made any false representation, the director, in consultation with the Inspector General, may assess a civil penalty of not more than $20,000. The penalty may be in addition to or in lieu of any other action that may be taken by the director, in consultation with the Inspector General, or any other board, court, or entity.

(b) Notwithstanding the existence or pursuit of any other remedy, the director, in consultation with the Inspector General, may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association, or corporation to restrain or prevent the establishment, conduct, management, or operation of any pain management clinic or violation of any provisions of this article, or any rule lawfully promulgated thereunder without first obtaining a license therefor in the manner

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hereinbefore provided.

(c) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the director, in consultation with the Inspector General, shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain management clinic's actions or the actions of the designated or practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(2) What actions, if any, the owner or designated physician took to correct the violations;

(3) Whether there were any previous violations at the pain management clinic; and

(4) The financial benefits that the pain management clinic derived from committing or continuing to commit the violation.

(d) Upon finding that a physician has violated the provisions of this article or rules adopted pursuant to this article, the director, in consultation with the Inspector General, shall provide notice of the violation to the applicable licensing board.

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§16B-7-9. Rules.

(a) The Inspector General, in collaboration with the West Virginia Board of Medicine and the West Virginia Board of Osteopathy, shall promulgate rules in accordance with the provisions of §29A-1-1 *et seq.* of this code for the licensure of pain management clinics to ensure adequate care, treatment, health, safety, welfare, and comfort of patients at these facilities. These rules shall include, at a minimum:

(1) The process to be followed by applicants seeking a license;

(2) The qualifications and supervision of licensed and nonlicensed personnel at pain management clinics and training requirements for all facility health care practitioners who are not regulated by another board;

(3) The provision and coordination of patient care, including the development of a written plan of care;

(4) The management, operation, staffing, and equipping of the pain management clinic;

(5) The clinical, medical, patient, and business records kept by the pain management clinic;

(6) The procedures for inspections and for the review of utilization and quality of patient care;

(7) The standards and procedures for the general operation of a pain management clinic, including facility operations, physical operations, infection control requirements, health and safety requirements, and quality assurance;

(8) Identification of drugs that may be used to treat chronic pain that identify a facility as a pain management clinic, including, at a minimum, tramadol and carisoprodol;

(9) Any other criteria that identify a facility as a pain management clinic;

(10) The standards and procedures to be followed by an owner in providing supervision, direction, and control of individuals employed by or associated with a pain management clinic;

(11) Data collection and reporting requirements; and

(12) Such other standards or requirements as the Inspector General determines are appropriate.

(b) The rules authorized by this section may be filed as emergency rules if deemed necessary to promptly effectuate the purposes of this article. The Legislature finds that the changes made to this article during the 2024 regular session of the Legislature constitute an emergency for the purposes of filing any amendment to existing rules.

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§16B-7-10. Advertisement disclosure.

Any advertisement made by or on behalf of a pain management clinic through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio, or television, or through written or recorded communication, concerning the treatment of chronic pain, as defined in §16B-7-2 of this code, shall include the name of, at a minimum, one physician owner responsible for the content of the advertisement.

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